

REMARKS

Reconsideration and removal of the grounds for rejection are respectfully requested.

Claims 1-7 and 11-14 were in the application, claims 1-7 and 11-14 have been cancelled and new claims 15-42 have been added.

The examiner should note that a revocation and new power of attorney form was submitted on July 7, 2004 in favor of the undersigned attorney.

In the Office Action dated February 24, 2004, the examiner objected to the drawings, and new drawings sheets are being submitted under separate cover which are believed to render moot the objections.

Claims 1 and 11-13 were rejected under 35 U.S.C. §102(b) as being anticipated by Yamaguchi, et al, EP734722.

To have anticipation, each and every element of the claim must be present in a single prior art reference. W.L. Gore & Assoc. V. Garlock, Inc. 220 USPQ 303 (Fed. Cir. 1983). In addition, the prior art reference must be enabling, thus placing the allegedly discussed matter in the possession of the public In re Brown, 141 USPQ 245 (CCPA) 1964).

Yamaguchi does not anticipate new claims 15-42. Claim 15 requires “a patch” having a “first surface having an adhesive on at least a portion thereof” for allowing the patch to be applied to the area to be heated. In Yamaguchi, with reference to Fig. 1, the patch corresponds to backing layer 2. No adhesive is provided on the backing layer 2. Rather the adhesive is provided “over the whole undersurface of the protective film 3” Col. 6, L. 54-56. This is necessary to allow the adhesive to be removed together with the layer 6 and a portion of the protective film 3, as it is an object to avoid interaction of the adhesive with the drug being dispensed. The adhesive is applied to, and not removed from, the first surface in the applicants’ invention.

Claim 15 further requires: “a dispensing container....retained on a portion of the first surface”. Yamaguchi has no such dispensing container. Rather, Yamaguchi provides a reservoir in the backing layer for receiving the substance. Though covered by a protective film, there is no “container” for holding a substance retained on a first surface of a patch as required by the present invention.

The examiner has also misinterpreted the prior art figures, specifically Fig. 9. In this embodiment, the substance is stored in a reservoir formed in the backing layer 2, covered by a permeable film layer 8, having a covering film 9 over that. Over all of these there is applied the adhesive layer 5. The examiner should note that such a construction was found unsuitable to use, having the worst drug retention, as it is represented by comparative example 2, and so such a structure, missing the discrete dispensing container of the applicant's invention, and the arrangement of a release member as well as a backing member, fails to disclose each and every element of the invention, and leads one away from the construction of Fig. 9 in any event, as the invention of Yamaguchi Fig. 1 is distinguished therefrom.

Clearly, none of the embodiments of Yamaguchi are enabling of applicant's invention, since none use a dispensing container retained on a first surface of a patch and a having release means for opening the container adjacent to or incorporating an applicator means therein, as does the arrangement of the applicant's invention, and new claims 15-42 are not anticipated thereby.

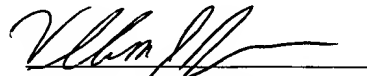
Claims 3-7 and 14 were rejected as being unpatentable over Yamaguchi in view of Sabatano. The examiner admits that Yamaguchi fails to disclose an absorbent pad. The examiner refers to Sabatano as teaching such a pad. However, there is no teaching or suggestion supporting the examiner's proposed combination, and even if made, would not result in the applicant's invention.

Note that the pad 13 is mounted onto a backing strip 11. An envelope 14 is utilized as part of a peelable backing layer so that it is removed, opened and the substance dispensed through an aperture 16 onto the gauze pad 13, and then discarded. Such an orientation of components is entirely contrary to the orientation of components in Yamaguchi, and there is no teaching or suggestion for picking the gauze pad of Sabatano and placing it, somehow, into the Yamaguchi assembly. This would be contrary to Yamaguchi, as Yamaguchi uses heat sealing between the films and the backing layer to isolate the substance, and a gauze pad cannot be applied in that way and is not easily substituted into the Yamaguchi assembly. Further, such a modification is not justified as use of a gauze pad would interfere with the drug delivery purpose of Yamaguchi, and likely increase, not decrease, losses due to leakage and evaporation. Even if accomplished, it still does not have the arrangement of components as in the present invention, as explained above.

As there is no teaching or suggestion supporting the combination, the rejection is improper and must be withdrawn.

Based on the above amendment and remarks, favorable consideration and allowance of the application are respectfully requested. However should the examiner believe that direct contact with the applicant's attorney would advance the prosecution of the application, the examiner is invited to telephone the undersigned at the number given below.

Respectfully submitted,



William J. Sapone

Registration No. 32,518

Attorney for Applicant(s)

COLEMAN SUDOL SAPONE P.C.

714 Colorado Avenue

Bridgeport CT 06605

Phone: (203) 366-3560

Fax: (203) 335-6779